3632. Adulteration of distilled water. U. S. v. 100 Vials * * *. (F. D. C. No. 31772. Sample No. 25740–L.)

LIBEL FILED: October 9, 1951, District of New Jersey.

ALLEGED SHIPMENT: On or about June 20, 1951, by the Harvey Laboratories, from Philadelphia, Pa.

PRODUCT: 100 vials of *distilled water* at Trenton, N. J.

LABEL, IN PART: "100 cc. Ampul-Vial Distilled Water Harvey (Triple Distilled) Sterilized."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Water for Injection," a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and its quality and purity fell below the official standard since it failed to meet the test for pyrogens laid down in such standard.

DISPOSITION: November 21, 1951. Default decree of condemnation. The court ordered that the product be destroyed, with the exception of 8 vials which were to be turned over to the Federal Security Agency.

3633. Adulteration and misbranding of Nervease headache powders. U. S. v. 12 Cartons * * *. (F. D. C. No. 31393. Sample No. 5645–L.)

LIBEL FILED: August 3, 1951, District of New Hampshire.

ALLEGED SHIPMENT: On or about May 25, 1951, by the Nervease Co., from Boston, Mass.

PRODUCT: 12 cartons, each containing 12 packages, of *Nervease headache powders* at Manchester, N. H. Examination showed that the product contained not more than 2.19 grains of acetanilid per powder.

LABEL, IN PART: (Package) "Nervease Headache Powders Active Ingredients: Acetanilid 2½ Grains Each Powder with Caffeine and Camphor * * * Contents 8 Powders."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported or was represented to possess, namely, 2½ grains of acetanilid per powder.

Misbranding, Section 502 (a), the designation "Nervease" appearing on the package label was false and misleading since such designation represented and suggested that the article was an adequate and effective treatment for nervous tension, whereas the article was not an adequate and effective treatment for such condition; and the label statement "Acetanilid 2½ Grains Each Powder" was false and misleading as applied to a product which contained less than the stated amount of acetanilid.

DISPOSITION: October 16, 1951. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

3634. Misbranding of Diaplex. U. S. v. 23 Cartons * * *. (F. D. C. No. 31705. Sample No. 13633–L.)

LIBEL FILED: September 17, 1951, District of Idaho.

*See also Nos. 3621, 3624–3626, 3629, 3631, 3633.

ALLEGED SHIPMENT: On or about August 27, 1951, by John McVey, also known as H. W. Pierce, from Carr, Colo.

PRODUCT: 23 12-ounce cartons of *Diaplex* at Emmett, Idaho. Examination showed that the product consisted of ground plant material derived from a species of saltbush such as *Atriplex canescens*.

LABEL, IN PART: "Diaplex for Diabetics * * * for further information address c/o H. W. Pierce, Wellington, Colo."

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements on the label of the article were false and misleading since they represented and suggested that the article was an adequate and effective treatment for diabetes, and that use of the article by diabetics would render treatment with insulin unnecessary, whereas the article was worthless in the treatment of diabetes: "Diaplex for Diabetics * * * A diabetic should drink * * * Diaplex * * * watch the urine test daily and you will be amazed at the results * * * Persons using Diaplex with insulin should make the urine test daily, and as the pancreas increases its normal functions, reduce the amount of insulin sufficiently to avoid insulin reaction. Only use enough insulin to take care of the surplus sugar, and eventually eliminate the insulin entirely. But continue the use of Diaplex until you are well and strong. Persons who have never used insulin, and not in coma, will find it unnecessary to do so. All that will be required is to adhere to a good diabetic diet and drink two quarts of Diaplex for a few months, and like thousands of others he, too, will rejoice in the grand activity of good health and vigor."

Further misbranding, Section 502 (e) (1), the label of the article failed to bear the common or usual name of the drug.

DISPOSITION: November 5, 1951. Default decree of forfeiture and destruction.

3635. Misbranding of d-alphatocopheryl acetate capsules (Daland's Vit E Min Gelucaps). U. S. v. 1 Unlabeled Paper Bag, etc. (F. D. C. No. 28479. Sample No. 48592–K.)

LIBELS FILED: December 13, 1949, District of Delaware; amended libels filed May 1 and July 12, 1951.

ALLEGED SHIPMENT: On or about September 23, October 21, and November 3, 1949, from Newark, N. J.

PRODUCT: *d-alphatocopheryl acetate capsules.* 1 unlabeled paper bag containing 1,000 capsules; 23 bottles, each containing 100 capsules; 4 bottles, each containing 50 capsules; 1 bottle containing 1,000 capsules; and 2 bottles, each containing 500 capsules, in possession of the Daland Vitamin Co., Wilmington, Del.

The capsules had been repacked into the paper bag and bottles from the bulk containers in which they had been shipped in interstate commerce.

LABEL, IN PART: (Bottles) "Daland's Vit E Min Gelucaps 100 Mg. [or "30 Mg."] Alpha-Tocopherol."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in a booklet entitled "Excerpts from the Treatment of Cardiovascular and Renal Diseases with Vitamin E 'Alpha Tocopherol,'" which accompanied the article were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for cardiovascular and renal diseases; that vitamin E therapy has the distinctive feature of improving the function of damaged hearts by attacking the underlying patho-